

WHAT IS CLAIMED IS:

1 1. A method of eliminating or reducing infection in a biological material,
2 the method comprising removing a binding site contained in the material so that an infectious
3 agent is prevented or inhibited from binding to the biological material.

1 2. The method of claim 1, wherein the infection is prion infection, and the
2 infectious agent is prion protein.

1 3. The method of claim 1, wherein the biological material is bioprosthetic
2 tissue.

1 4. The method of claim 3, wherein the structural integrity of the tissue is
2 maintained.

1 5. The method of claim 3, further comprising contacting the bioprosthetic
2 tissue with a preparation comprising a surfactant.

1 6. The method of claim 3, further comprising contacting the bioprosthetic
2 tissue with a preparation comprising a surfactant and a denaturing agent.

1 7. The method of claim 6, wherein the surfactant is Tween 80.

1 8. The method of claim 6, wherein the denaturing agent is a protic
2 solvent.

1 9. The method of claim 8, wherein the protic solvent is an alcohol.

1 10. The method of claim 9, wherein the alcohol is ethanol or isopropanol.

1 11. The method of claim 6, wherein the preparation further comprises an
2 cross linking agent.

1 12. The method of claim 11, wherein the cross linking agent is an
2 aldehyde.

1 13. The method of claim 12, wherein the aldehyde is formaldehyde or
2 glutaraldehyde.

1 14. The method of claim 1, wherein the infectious agent binding site is
2 comprised of phospholipid.

1 15. The method of claim 14, wherein the phospholipid is selected from the
2 group consisting of phosphatidylinositol, phosphatidylethanolamine,
3 gangliotetraosylceramide, phosphatidylserine, phosphatidylcholine, phosphatidic acid, and
4 sphingomyeline.

1 16. The method of claim 14, further comprising contacting the tissue with
2 a preparation including a phospholipase.

1 17. The method of claim 1, further comprising contacting the bioprosthetic
2 tissue with a preparation comprising formaldehyde, ethanol, and Tween 80.

1 18. The method of claim 2, wherein the prion protein further comprises
2 prion-precursor protein.

1 19. The method of claim 1, further comprising a terminal sterilization step.

1 20. The method of claim 1, further comprising washing the tissue to
2 promote removal of the prion protein.

1 21. A method of treating a biological material, the method comprising
2 removing a binding site contained in the material so that an unwanted protein is prevented or
3 inhibited from binding to the biological material.

1 22. The method of claim 21, wherein the unwanted protein is selected from
2 the group comprising alkaline phosphatase, Thy-1, and acetylcholinesterase.

1 23. A method of eliminating or reducing infection in a biological material,
2 the method comprising removing a binding site comprising binding site a protein or
3 polysaccharide, contained in the material so that an infectious agent is prevented or inhibited
4 from binding to the biological material.

1 24. The method of claim 23, wherein the infection is prion infection, and
2 the infectious agent is prion protein.

1 25. The method of claim 23, wherein the structural integrity of the tissue is
2 maintained.

1 26. The method of claim 23, further comprising contacting the
2 bioprosthetic tissue with a preparation comprising an enzyme that digests the binding site.

1 27. The method of claim 26, wherein the preparation comprises
2 heparinase, in an amount effective to remove the binding site.

1 28. The method of claim 23, further comprising contacting the
2 bioprosthetic tissue with a preparation comprising a solvent, a surfactant, or a chaotropic
3 agent in an amount effective to extract the binding site from the tissue.

1 29. The method of claim 23, further comprising contacting the
2 bioprosthetic tissue with a preparation that chemically derivatizes a polycationic site, thereby
3 eliminating the binding site from the tissue.

1 30. The method of claim 23, wherein the binding sites has binding affinity
2 to exogenous prion protein.

1 31. The method of claim 23, further comprising contacting the tissue with
2 a preparation that has binding affinity for endogenous prion protein, so that a bound complex
3 is formed between the preparation and the endogenous prion protein.

1 32. The method of claim 31, further comprising a washing step to remove
2 the bound complex from the tissue.

1 33. A method of eliminating or reducing infection in a bioprosthetic tissue,
2 the method comprising blocking a binding site contained in the tissue so that an infectious
3 agent is prevented or inhibited from binding to the binding site.

1 34. The method of claim 33, wherein the infection of prion infection, and
2 the infectious agent is prion protein.

1 35. The method of claim 33, wherein the structural integrity of the tissue is
2 maintained.

1 36. The method of claim 33, wherein the blocking step further comprises
2 contacting the bioprosthetic tissue with a preparation comprising one or more polysulfonated
3 polyglycosides.

1 37. The method of claim 36, wherein the one or more polysulfonated
2 polyglycosides are selected from a group consisting of pentosan polysulfate, sulfated
3 colomycin, dextran sulfate, sulfated carageenans, and heparin/heparan sulfate.

1 38. The method of claim 36, wherein the contacting step is performed at a
2 temperature of about 37° C.

1 39. The method of claim 33, wherein the contacting step promotes the
2 dissociation of prion protein from the bioprosthetic tissue.

1 40. A method of eliminating or reducing infection in a bioprosthetic tissue,
2 the method comprising blocking an infectious agent so that the infectious agent is prevented
3 or inhibited from binding to a binding site in the tissue.

1 41. The method of claim 40, wherein the infection is prion infection, and
2 the infectious agent is prion protein.

1 42. The method of claim 40, wherein the blocking step further comprises
2 contacting the bioprosthetic tissue with a preparation comprising a compounds selected from
3 tetrasubstituted porphyrin, polyanionic fungal agent, congo red, fast red, trypan red and
4 combinations thereof.

1 43. The method of claim 40, wherein the method is performed before,
2 during, or after fixation.

1 44. The method of claim 40, wherein the method is performed during
2 bioburden reduction.

1 45. The method of claim 40, wherein the method is performed during final
2 sterilization.

1 46. The method of claim 40, wherein the method is performed during
2 packaging.

1 47. The method of claim 46, further comprising storing the tissue in the
2 preparation.

1 48. The method of claim 42, wherein the preparation further comprises one
2 or more cross-linkable groups that prevent or inhibit dissociation of the one or more
3 polysulfonated polyglycosides.

1 49. The method of claim 48, wherein the cross-linkable group is selected
2 from a group consisting of lysine groups and azide moieties.

1 50. A method of eliminating or reducing calcification in a biological
2 material, the method comprising removing a phospholipid calcium nucleation site contained
3 in the material so that calcium is prevented or inhibited from binding to the biological
4 material.

1 51. The method of claim 50, wherein the biological material is
2 bioprosthetic tissue.

1 52. The method of claim 50, wherein the structural integrity of the
2 bioprosthetic tissue is maintained.

1 53. The method of claim 51, further comprising contacting the
2 bioprosthetic tissue with a preparation comprising a surfactant.

1 54. The method of claim 51, further comprising contacting the
2 bioprosthetic tissue with a preparation comprising a surfactant and a denaturing agent.

1 55. The method of claim 54, wherein the surfactant is Tween 80.

1 56. The method of claim 54, wherein the denaturing agent is a protic
2 solvent.

1 57. The method of claim 54, wherein the preparation further comprises an
2 cross linking agent.

1 58. The method of claim 50, wherein the phospholipid is selected from the
2 group consisting of phosphatidylinositol, phosphatidylethanolamine,

3 gangliotetraosylceramide, phosphatidylserine, phosphatidylcholine, phosphatidic acid, and
4 sphingomyelin.

1 59. The method of claim 53, further comprising contacting the tissue with
2 a preparation including a phospholipase.

1 60. The method of claim 50, further comprising contacting the
2 bioprosthetic tissue with a preparation comprising formaldehyde, ethanol, and Tween 80.

1

FOI b7 - 4294000